K130577

MicroVention
TERUMO

JUN 17 2013

510(K) Summary

Trade Name: AZUR Coil System – Pushable 18 & 35

Generic Name: Vascular Embolization Device

Classification: Class II, 21 CFR 870.3300

Submitted By: MicroVention, Inc.
1311 Valencia Avenue
Tustin, California U.S.A.

Contact: Cynthia Valenzuela

Predicate Device:

Number	Description	Clearance Date
K071939	HydroCoil Embolic System (HES) – HydroFrame	22APR2010
K091882	AZUR Peripheral HydroCoil Endovascular Embolization Coil System – Pushable 18	08JUL2009
K050954	MicroPlex Coil System (MCS) and HydroCoil Embolic System (HES)	28JUN2005

Device Description

The AZUR Pushable 18 & 35 coils are made of platinum alloy (Pt/W: 92/8) with an outer layer of hydrogel polymer with an added over-coil. The over-coil is comprised of a 0.00125" platinum alloy (Pt/W: 92/8) wire which is wound over the hydrogel polymer and two ends are bonded to the main coil with the same DYMAX adhesive used in the existing AZUR Pushable 18 & 35 coils. The over-coil materials and manufacturing processes are also the same as those used in the manufacture of the HES (K0509054) coils.

The implant segment is then attached to the delivery pusher. The pusher is inserted into detachment controller which when activated detaches the coil from the delivery pusher. The detachment controller utilizes battery power to detach the coils from the delivery pusher.

MicroVention
TERUMO

Indication For Use

The intended use as stated in the product labeling is as follows:

The AZUR System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature

Verification and Test Summary Table

Bench Testing	**Result**
Simulated Use	Met established criteria
Advancement / Retraction Force	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the AZUR Coil System - Pushable 18 & 35 line extension coils when compared with the predicate devices, MicroVention AZUR Peripheral HydroCoil Endovascular Embolization Coil System – Pushable 18 & 35 (K071939, K091882) and HydroCoil Embolic System (K050954).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the AZUR Coil System - Pushable 18 & 35 Coils described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2013

Microvention, Inc.
Attention: Cynthia Valenzuela
1311 Valencia Avenue
Tustin, CA 92780

Re: K130577
Trade/Device Name: Azur Pushable 18 and 35 System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: May 17, 2013
Received: May 22, 2013

Dear Ms. Valenzuela:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K130577

Device Name: AZUR Peripheral Coil System (Pushable) 18 & 35 System

Indications For Use:

The AZUR System is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
2013.06.17 08:19:09 -04'00'